

PATENT APPLICATION

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of

Docket No: Q55432

Nobuhiko OGURA

Appln. No.: 09/373,585

Group Art Unit: 1634

Confirmation No.: 2737

Examiner: Frank Wei Min LU

Filed: August 13, 1999

For: TEST PIECE, METHOD OF AND APPARATUS FOR MANUFACTURING THE TEST
PIECE AND METHOD OF AND SYSTEM FOR READING THE SAME

REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents

P.O. Box 1450

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Sir:

In accordance with the provisions of 37 C.F.R. § 41.41, Appellant respectfully submits
this Reply Brief in response to the Examiner's Answer dated July 6, 2007. Entry of this Reply
Brief is respectfully requested.

Table of Contents

STATUS OF CLAIMS	2
GROUND OF REJECTION TO BE REVIEWED ON APPEAL	3
ARGUMENT.....	4
CONCLUSION	15

STATUS OF CLAIMS

The status of the claims remains unchanged as set forth in the Appeal Brief filed February 28, 2007.

Claims 6, 7 and 21-33 are pending in the present application and stand finally rejected and are the claims being appealed in the present application.

Claims 1-5 and 8-20 have been canceled from the application.

In the Office Action of November 30, 2006, claims 6, 7, 21, 22, 25-29 and 31-33 have been newly rejected under 35 U.S.C. § 102(e) as being anticipated by Stimpson (U.S. Patent No. 6,037,186; hereinafter "Stimpson"). In the Advisory Action of February 24, 2006 and the Office Action of July 27, 2005, claims 6, 7, 21, 22, 25-29 and 31-33 were originally rejected under 35 U.S.C. § 102(e) as being anticipated by Stimpson as evidenced by Hayes et al. (U.S. Patent No. 4,877,745; hereinafter Hayes).

Claims 23 and 24 have been newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Stimpson in view of Shuminov (U.S. Patent No. 5,808,554; hereinafter "Shuminov"). Claims 23 and 24 were originally rejected under 35 U.S.C. § 103(a) as being unpatentable over Stimpson in view of Hayes and further in view of Shuminov.

Claim 30 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stimpson in view of Shuminov and further in view of Biedermann et al. (U.S. Patent No. 4,881,439; hereinafter Biedermann).

No other ground of rejection or objection is currently pending.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 6, 7, 21, 22, 25-29 and 31-33 have been newly rejected under 35 U.S.C. § 102(e) as being anticipated by Stimpson. Claims 6, 7, 21, 22, 25-29 and 31-33 were originally rejected under 35 U.S.C. § 102(e) as being anticipated by Stimpson as evidenced by Hayes.

2. Claims 23 and 24 have been newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Stimpson and further in view of Shuminov. Claims 23 and 24 were originally rejected under 35 U.S.C. § 103(a) as being unpatentable over Stimpson in view of Hayes and further in view of Shuminov.

3. Claim 30 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stimpson in view of Shuminov and further in view of Biedermann.

ARGUMENT

Appellant now responds to the new points raised by the Examiner in his Answer.

I. Structural language in the preamble of claim 6 should be given due consideration

On page 5 of the Office Action, the Examiner asserts that the language “for manufacturing a test piece for use in biological analysis of a sample organism comprising a strip-like substrate bearing thereon numbers of known specific binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate” is merely intended use and is not a structural limitation.

The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). Further, during examination, statements in the preamble reciting the purpose or intended use of the claimed **invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference** (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). **Any terminology in the preamble that limits the structure** of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). MPEP 2111.02.

Further, "[i]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is '**necessary to give life, meaning, and vitality**' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003). *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).

Further, where reference throughout the rest of the claim relies on the language of the preamble and derive antecedent basis from the preamble language, the preamble language therefore limits the language of the claim. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995).

In the present situation, the language "for manufacturing a test piece for use in biological analysis of a sample organism comprising a strip-like substrate bearing thereon numbers of known specific binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate" clearly recites structural limitations of the claimed invention. Further, the body of the claim relies on the

language of the preamble to define the language in the body of the claim. Therefore, the language in the preamble must be given due consideration.

II. Functional language of the claims should be given due consideration

On page 7 of the Office Action, the Examiner asserts that the claims directed to an apparatus should be distinguished from the prior art in terms of structure rather than function. Therefore, the Examiner asserts that the language “each of said plurality of applicators respectively operable to apply one of the plurality of known specific binding agents on the sheet-like substrate”, “conveys the plurality of applicators or the sheet-like substrate relative to each other in a second direction which is substantially perpendicular to the first direction while the applicators apply the plurality of known specific binding agents, thereby applying the plurality of known specific binding agents in lines which extend in the second direction and are arranged at predetermined intervals in the first direction”, and “which cuts the sheet-like substrate bearing thereon the plurality of specific binding agents in the first direction into a plurality of strips” is merely functional.

However, Appellant submits that a functional limitation must be evaluated and considered just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. MPEP 2173.05(g). Therefore, due consideration should be given to the functional language of the claims.

III. The claimed applicator means and conveyor means are not disclosed in the Stimpson Reference

Claim 26 recites:

a plurality of **applicator means** arranged at predetermined interval in a first direction relative to a sheet-like substrate...a conveyor means which conveys the plurality of applicators or the sheet-like substrate relative to each other in a second direction which is substantially perpendicular to the first direction **while the applicators apply the plurality of known specific binding agents**, thereby applying the plurality of known specific binding agents in lines which extend in the second direction and are arranged at predetermined intervals in the first direction..

On page 9 of the Examiner's Answer, the Examiner asserts that a means or step plus function limitation should be interpreted in a manner consistent with the specification disclosure. The Examiner then goes on to say that if the specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of the limitation.

In construing a means plus function limitation, the Examiner should look to the specification and identify the corresponding structure for that function. MPEP 2182. In the present situation, Appellant has directed the Examiner to, for example, page 16, line 26 to page 18, line 4 of Appellant's specification, which describes the claimed applicator means and conveyor means. Specifically, that the applicator ports and conveyor belt disclosed in Appellant's specification discloses the claims applicator means and conveyor means, respectively.

Further, the corresponding structure for the means plus language of the claims was clearly identified in the “Summary of the Claimed Subject Matter” as indicated in the Appellant’s Appeal Brief.

In view of the forgoing, Appellant submits that the use of reagent jet printing in Stimpson does not teach the claimed applicator means which are “arranged at predetermined interval in a first direction relative to a sheet-like substrate each of said plurality of applicators respectively operable to apply one of the plurality of known specific binding agents on the sheet-like substrate” as claimed. Further, Appellant submits that the X-Y-Z table of Stimpson does not teach “a conveyor means which conveys the plurality of applicators or the sheet-like substrate relative to each other in a second direction which is substantially perpendicular to the first direction while the applicators apply the plurality of known specific binding agents, thereby applying the plurality of known specific binding agents in lines which extend in the second direction and are arranged at predetermined intervals in the first direction” as claimed.

Further, although Stimpson discloses a razor blade, Stimpson does not disclose “a cutting means which cuts the sheet-like substrate bearing thereon the plurality of specific binding agents in the first direction into a plurality of strips,” as claimed.

On page 14 of the Examiner’s Answer, the Examiner asserts that Stimpson, col. 7, lines 19-48; col. 8, third paragraph, and Fig. 2A, discloses using a reagent jet printer and lines of different DNA samples are applied to the sheet in lines or otherwise a pin applicator so that multiple dots from the pin overlap to form a line wherein the different reagent lines on the sheet are formed as close together as possible and with minimum line width allowed by the printing

method so that array density is maximized. Therefore, the Examiner asserts that Stimpson must disclose a plurality of application means (i.e. reagent dispensers) which are arranged at predetermined intervals in order to apply lines of different DNA samples.

However, as previously submitted, Stimpson merely indicates the use of, for example, a reagent jetting printer. There is no indication that the reagent jetting printer of Stimpson includes applicators arranged and conveyed, as recited in claim 26. Therefore, there is no teaching in Stimpson, that a plurality of applicator means are arranged at predetermined interval in a first direction relative to a sheet-like substrate. The Examiner is merely making assumptions regarding the reference. There is no support in the reference for the Examiner's conclusions therefore, the anticipation rejection is deficient.

The Examiner further asserts that since the specification does not define a conveyor means, therefore a conveyor can be considered as an apparatus for moving material from one point to another in a continuous fashion. As discussed above, a conveyor means is clearly disclosed in the Appellant's specification and figures.

The Examiner states that Stimpson discloses an automated device to apply the multitude of reagents to a 21.5 foot feet is assembled from an X-Y-Z table, therefore, the Examiner asserts that Stimpson discloses a conveyor means which conveys a plurality of applicators in a second direction which is substantially perpendicular to the first direction.

However, contrary to the Examiner's assertions, Stimpson does not teach a conveyor means which conveys the plurality of applicators or the sheet-like substrate relative to each other

in a second direction which is substantially perpendicular to the first direction while the applicators apply the plurality of known specific binding agents.

On page 24 of the Office Action, the Examiner asserts that although the specification discloses applicators ports and a conveyor belt, the specification does not define applicator ports as applicator means and does not define a conveyor belt as a conveyor means.

However, Appellant submits that the specification is not required to recite the claimed applicator "means" and the conveyor "means."

The "means or step plus function" limitation should be interpreted in a manner **consistent with the specification disclosure**. The Federal Circuit explained the two step analysis involved in construing means-plus-function limitations in *Golight Inc. v. Wal-Mart Stores Inc.*, 355 F.3d 1327, 1333-34, 69 USPQ2d 1481, 1486 (Fed. Cir. 2004):

The first step in construing a means-plus-function claim limitation is to define the particular function of the claim limitation. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376 [58 USPQ2d 1801, 1806] (Fed. Cir. 2001). "The court must construe the function of a means-plus-function limitation to include the limitations contained in the claim language, and only those limitations." *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 [63 USPQ2d 1725, 1730] (Fed. Cir. 2002)... The next step in construing a means-plus-function claim limitation is to look to the **specification and identify the corresponding structure for that function**. "Under this second step, 'structure disclosed in the specification is "corresponding" structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.'" *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 [68 USPQ2d 1263, 1267] (Fed. Cir. 2003) (quoting *B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 [43 USPQ2d 1896, 1900] (Fed. Cir. 1997)).

Based upon the foregoing, Appellant submits that the specification is not required to recite a conveying "means" and an applicator "means" as suggested by the Examiner. Therefore,

Appellant submits that the conveyor belt and the applicator ports correspond to the claimed conveying means and applicator means.

IV. Stimpson does not disclose the claimed cutting means

On page 18 of the Examiner's Answer, the Examiner asserts that a cutting means is not defined in the specification. However, contrary to the Examiner's assertion, the specification discloses a cutting means (e.g. Fig. 3, guide rail 60 and cutter edge 61). Further, the cutting means was identified in the "Summary of the Claimed Subject Matter" as indicated in the Appellant's Appeal Brief.

The Examiner continues to assert that the razor of Stimpson teaches the claimed cutting means. The Examiner states that although cutting is performed on a rod-shaped sheet in Stimpson, that Appellant has provided no evidence to show that the razor of Stimpson cannot cut a sheet-like substrate into a plurality of strips.

The razor of Stimpson cuts a rod-shaped sheet into a circular array. See Stimpson Figs. 1B and 1B. Therefore, the razor of Stimpson would not cut a sheet-like substrate into a plurality of strips.

Further, as previously submitted by the Appellant, merely because the razor of Stimpson is capable of cutting a rod-shaped sheet, does not mean that the razor of Stimpson would be capable of cutting a sheet-like substrate.

In *A.J. Deer Co. v. U.S. Slicing Mach. Co.*, 21 F.2d 812, 813 (7th Cir. 1927), the court determined that the Defendant's sawmill dog was non-analogous to the Plaintiff's meat cutting device. The sawmill dog was used for cutting logs which are generally of a large dimension both

in length and diameter, are hard in substance and would have to be supported differently from, for example, meat. On the other hand, the Plaintiff's meat cutting device, was used to cut meat, which is soft and pliable and requires little holding strength, and was not capable of holding large pieces.

Therefore, Appellant submits that the cutting device of Stimpson is non-analogous to the claimed cutting means. In the present case, the razor of Stimpson is used to cut a sheet **which is rolled into a rod shape**, similar to a log shape, having a large diameter. The claimed cutting means cuts a sheet-like substrate, **which is flat** and would have to be supported differently from a rod shaped array, as disclosed in Stimpson. Consequently, it would not be obvious to one of skill in the art to apply the razor of Stimpson which is used to cut a rod shape array to cut the claimed sheet-like substrate.

Therefore, Appellant submits that the Examiner has not shown that the razor of Stimpson, which is used to cut a rod-shaped sheet, is capable of cutting a sheet-like substrate into a plurality of strips.

V. Shuminov is non-analogous art

On page 24 of the Examiner's Answer, the Examiner asserts that since both Stimpson and Shuminov teach a conveyor, Stimpson and Shuminov are analogous art.

As indicated by the Examiner, "[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

Shuminov is directed to “Moisture Detecting Liner for a Diaper and a Process for Manufacture Thereof”. Shuminov is clearly not directed to a test piece and a method and apparatus for manufacturing the test piece for use in DNA analysis as disclosed in the Appellant’s invention. Therefore, Shuminov is not in the field of the Appellant’s endeavor.

Further, Shuminov is directed to moisture sensing pads for sensing moisture and such pads are used in disposable diapers. The goal of Shuminov is to detect wetness in a diaper. See Shuminov; col. 1, lines 1-15. The Appellant’s invention is directed to manufacturing a test piece which is easy to manufacture and easy to handle in biological analysis. See page 3, lines 14-16 of Appellant’s specification. Therefore, Shuminov, which is directed to determining wetness in a diaper, is not reasonably pertinent to the manufacture of a test piece for DNA analysis.

In view of the foregoing, Appellant submits that Shuminov is not analogous art.

VI. The combination of the guide rail of Shuminov or Biedermann with Stimpson is contrary to the principle of operation of Stimpson

The Examiner cited Shuminov guide rail 50 for teaching the claimed guide rail and cited the razor of Stimpson for teaching the claimed cutting means. However, Stimpson col. 14, lines 51-60, describes that the spiral bundle is placed inside a **metal tube** whose inner diameter is slightly larger than the outer diameter of the bundle. The bundle is allowed to extend from the end of the metal tube and an array slab was cut with a razor blade using the **metal tube** as a guide to obtain a uniform straight cut. Therefore, it is unlikely that one of skill in the art would modify the cutting guide of Stimpson to include the guide rail 50 of Shuminov or the guide rail of Biedermann.

Specifically, Stimpson clearly discloses the use of a metal tube as a guide. Therefore, to use the guide rail of Shuminov or Biedermann is clearly contrary to the explicit teachings of Stimpson which uses a metal tube as a guide. Consequently, modifying Stimpson to include the guide rail of Shuminov or Biedermann is contrary to the principle teaching of a metal tube as a guide, which is taught in Stimpson.

For at least the above reasons and those set forth in the Appeal Brief, claims 6, 7 and 21-33 should be deemed allowable.

REPLY BRIEF UNDER 37 C.F.R. § 41.41
U.S. Appln. No.: 09/373,585

Attorney Docket No. Q55432

CONCLUSION

For the above reasons as well as the reasons set forth in Appeal Brief, Appellant respectfully requests that the Board reverse the Examiner's rejections of all claims on Appeal. An early and favorable decision on the merits of this Appeal is respectfully requested.


Respectfully submitted,

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